

*REMARKS/ARGUMENTS**The Pending Claims*

Upon entry of this amendment, claims 1, 2, 9, 13, 23 and 42-57 will be pending. The pending claims are directed to an isolated or purified nucleic acid molecule that encodes a polypeptide comprising SEQ ID NO: 2, and methods relating thereto.

The Amendments to the Claims

Claims 3-8, 10-12, 14-22, and 24-41 have been cancelled in response to the restriction requirement as being drawn to a nonelected invention. Cancellation of any subject matter should not be construed as abandonment of that subject matter, and Applicants reserve the right to pursue any cancelled subject matter in a continuation, continuation-in-part, divisional, or other application.

Claim 1 has been amended to incorporate the subject matter of claim 2, in part. Claim 2 has been amended to recite that the nucleic acid molecule comprises SEQ ID NO: 1. This amendment is supported by the original claims and the specification at, for example, paragraphs [0018] and [0028], and Figure 1A. Claim 13 has been amended to refer to an “isolated” cell. Claim 23 has been amended to recite the detection of a nucleic acid comprising SEQ ID NO: 1, to delete the term “male,” and to correct matters of form. Claim 24 has been cancelled. Claims 42-57 are new and are supported by the original claims and specification at, for example, paragraphs [0064]-[0071] and [0092], and the Examples.

Accordingly, no new matter has been added by way of these amendments.

The Office Action

The Office Action objects to the specification for the use of trademarks that are not capitalized and/or do not include the trademark symbol. The Office Action objects to claim 23 as drawn in part to a non-elected invention. The Office Action rejects claims 1, 2, 9, 13, and 23 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Office Action rejects claims 1, 9, 13, and 23 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The Office Action rejects claims 2, 23, and 24 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The Office Action rejects claim 13 under

35 U.S.C. § 101 as allegedly encompassing non-statutory subject matter. Reconsideration of the objections and rejections is respectfully requested.

Discussion of Objections to Specification and Claims

The Office Action objects to the specification for the inclusion of trademarks that are not capitalized and/or do not include the trademark symbol. The specification has been amended such that all trademarks are capitalized and include the appropriate trademark symbol.

The Office Action objects to claim 23 because it allegedly is drawn in part to a non-elected invention. Claim 23 has been amended to conform to the restriction requirement.

In view of the foregoing, the objections to the specification and claims should be withdrawn.

Discussion of Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claims 1, 2, 9, 13, and 23 under Section 112, second paragraph, as allegedly indefinite. In particular, the Office Action contends that the term “brother of regulator of imprinted sites (BORIS)” is merely a laboratory distinction and cannot be used as the sole means for identifying the claimed nucleic acid sequence. In addition, the Office Action alleges that the term “highly stringent conditions” in claim 2 is unclear. Claim 23 allegedly is unclear for reciting the phrase “which method” instead of “said method.”

Applicants’ disagree with the Section 112, second paragraph rejections. Nevertheless, the allegedly objectionable language has been removed from the claims in order to expedite prosecution. Accordingly, the Section 112, second paragraph, rejections should be withdrawn.

Discussion of Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

The Office Action rejects claims 1, 9, 13, and 23 under Section 112, first paragraph, as allegedly lacking written description. In essence, the Office Action contends that the specification does not disclose a representative number of species to support the claimed genus of BORIS fragments comprising 1536 contiguous nucleotides.

Applicants disagree with the rejection. However, in an effort to advance prosecution of the present application, and not in acquiescence of the rejection, independent claims 1 and 23 have been amended to recite a nucleic acid comprising a sequence that encodes SEQ ID NO: 2, or a nucleic acid comprising SEQ ID NO: 1. In view of these amendments, the written description rejection is believed to be moot and should be withdrawn.

Discussion of Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

The Office Action rejects claims 2, 23, and 24 under Section 112, first paragraph, for an alleged lack of enablement. While the Office Action acknowledges that the present specification enables a polypeptide of SEQ ID NO: 2, the nucleic acid sequence of SEQ ID NO: 1, a nucleotide sequence that encodes SEQ ID NO: 2, and a method of detecting BORIS in cancer cell lines, the specification allegedly does not enable a nucleic acid sequence that is at least 45% identical to SEQ ID NO: 1, or a method of diagnosing a cancer or a predisposition to cancer.

Solely in an effort to advance prosecution of the subject invention, and not in acquiescence of the rejection, claim 2 has been amended to recite that the isolated or purified nucleic acid molecule of claim 1 comprises SEQ ID NO: 1. Also, claim 24 has been cancelled. Thus, the enablement rejection as to claims 2 and 24 are believed to be moot.

With respect to claim 23 (and claims depending therefrom), the rejection is traversed. Contrary to the assertion of the Office Action, the claimed method of diagnosing a cancer or a predisposition to a cancer in a mammal is enabled by the present specification, as evidenced by the specification itself, and by post-filing publications that further support the validity of the assertions made in the present application. In particular, the specification discloses that BORIS, which is normally a testes-specific gene, is expressed in a variety of cancer cell lines, including breast cancer cell lines (see Example 5 and Table 1). BORIS expression also has been detected in primary tumor samples (e.g., Wilms tumor samples and breast tumor samples), which correlated with BORIS expression in cancer cell lines (see specification at, e.g., paragraph [00121]).

The correlation of BORIS gene expression with cancer in cancer patients has been further demonstrated by Risinger et al, *Clin. Cancer Res.*, 13(6): 1713-19 (2007) and D'Arcy et

al, *Clin. Cancer Res.*, 12(20): 5978-5986 (2006) (see accompanying Information Disclosure Statement). Risinger et al. discloses a high incidence of BORIS gene expression in uterine/endometrial cancers. D'Arcy et al. discloses that BORIS is expressed at high levels in leukocytes obtained from whole blood of breast cancer patients (Abstract). These results support the assertions of the present application that BORIS expression can be used as a clinical cancer marker in various cancers, and that the detection of BORIS can be facilitated using blood or tissue (somatic) samples.

Therefore, using the guidance provided by the specification, one of ordinary skill in the art would be able to practice the method of claim 23 without undue experimentation. In view of the foregoing, the pending claims are enabled by the present specification. Thus, Applicants request that the enablement rejection be withdrawn.

Discussion of Rejection Under 35 U.S.C. § 101

The Office Action rejects claim 13 under Section 101 because the subject matter of the claim allegedly is not distinguishable from naturally-occurring cells. Applicants disagree with the rejection. Naturally-occurring cells would not contain a vector comprising a nucleic acid molecule encoding a BORIS polypeptide. Nevertheless, claim 13 has been amended to refer to an "isolated" cell, thereby obviating the Section 101 rejection.

Discussion of New Claims 50-57

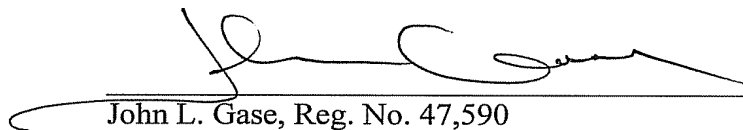
New claims 50-57 are directed to a method of detecting expression of a nucleic acid encoding SEQ ID NO: 2 in a mammal. The method comprises contacting a test sample from the mammal with a nucleic acid that specifically binds to SEQ ID NO: 2, and detecting hybridization with a nucleic acid of the test sample. The rejections set forth in the Office Action do not appear relevant to new claims 50-57. Applicants submit that the new claims are adequately described and enabled by the present application.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the

prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John L. Gase", is written over a horizontal line.

John L. Gase, Reg. No. 47,590
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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